

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Laboratories Administration

MJ02.01

FY2007

I. Overview

Brief Description of the Administration

The mission of the Laboratories Administration is to help promote, protect, and preserve the health and well-being of the people in Maryland from the consequences of communicable diseases, treatable hereditary disorders, environmental hazards, and from unsafe food and consumer products by promoting and enforcing standards of quality and care in cooperation with both public and private agencies at the local, state and federal levels.

The Laboratories Administration, established in 1898 as the Bureau of Bacteriology, is the oldest continuously operating entity within DHMH. The Administration operates a central public health laboratory in Baltimore and regional public health laboratories in Salisbury, Cheverly, and Cumberland. In FY2007 the Administration will have 275.28 authorized laboratory scientists and support staff (272.5 permanent and 2.78 contractual). In FY2005 the Administration performed 9.1 million tests.

The 12 Core Functions of our State Public Health Laboratory System

- **Disease surveillance** to assess, prevent, and control infectious, genetic, and chronic diseases, and exposure to environmental toxicants
- **Integrated data management** to capture and communicate data for public health decision-making
- **Reference and specialized testing** to identify unusual pathogens, verify results of other laboratory tests, and perform tests not usually performed in the private sector
- **Environmental health and protection** to identify potential health threats and ensure compliance with environmental regulations
- **Food safety** assurance by testing samples from people, food, and beverages implicated in foodborne illness, chemical contamination, and radiation
- **Drug safety** by inspecting pharmacies and issuing licenses for controlled dangerous substances
- **Laboratory quality assurance and regulation** of medical laboratories, physician office laboratories, job-related drug testing, and tissue banks
- **Policy development**, including standards for all health-related laboratories and input into State and federal public health policies
- **Emergency and terrorism preparedness** and response, requiring the infrastructure to analyze unknown samples for infectious, toxic, radioactive materials
- **Public health laboratory applied research** to improve the practice of public health laboratory science
- **Recruiting and training** the next generation of public health laboratory scientists
- **Partnerships and communication** with public and allied health groups, academia, professional organizations, private industry, etc. to support the core functions outlined above.

Major Programs of the Laboratories Administration

- Executive Direction (GF)
- Administrative and Support Services (GF)
- Laboratory Safety and Quality Assurance (GF)
- Bioterrorism Preparedness and Response (GF/FF)
- Chemical Terrorism Preparedness and Response (GF/FF)
- Emerging Infections Program (FF)
- Sexually Transmitted Disease Prevention (GF/FF)
- Epidemiology and Laboratory Capacity (FF)
- Public Health Microbiology (GF/FF/SF)
- Virology and Immunology (GF)
- Newborn Screening (GF/FF)
- Molecular Biology (GF)
- Childhood Lead Poisoning Prevention (GF)
- Drug Control (GF)
- Drinking Water Testing (RF)
- Environmental Chemistry (GF/RF)
- Radiation Chemistry (GF/RF)
- Air Quality Control (RF)
- Environmental Public Health Tracking (FF)
- Environmental Microbiology (GF/RF)
- HIV Testing (FF/RF)
- Eastern Shore Regional Laboratory (GF)
- Southern Maryland Regional Laboratory (GF)
- Western Maryland Regional Laboratory (GF)

Cost Containment Initiative Measure for FY2007

The Laboratories Administration will increase General Fund revenue by raising the fee for a controlled dangerous substance (CDS) certificate. This additional revenue will be used to offset a 3% (\$500,000) general cost containment placed on the Laboratories Administration.

Fiscal Year 2005 Performance (MFR) Goals

Goal 1. Adopt cutting edge technology to improve public health lab practice:

- Obj. 1.1 Developed two new tests based on genetic amplification techniques:
 - 1) Rapid identification of pertussis (whooping cough) by RT-PCR
 - 2) Rapid identification of adenovirus by RT-PCR
- Obj. 1.2 Maintained PFGE (Pulse Field Gel Electrophoresis) to identify 988 potential agents of foodborne and infectious diseases

Goal 2. Maintain and improve newborn screening for genetic disorders:

- Obj. 2.1 Increased the number of tests performed from 6.95 to 7.99M
- Obj. 2.2 Maintained reporting turn-around-time for abnormal results to 48 hours and normal test results to 3 business days

Goal 3. Expand laboratory preparedness & response to bioterrorism

- Obj. 3.1 Clinical labs in MD linked to the MD Lab. Response Network
All 58 labs maintained in the MD Lab Response Network
- Obj. 3.2 No. of tests performed on potential bioterrorism and chemical terrorism samples: BT samples: 313
CT samples: 1

Goal 4. Promote quality and reliability of lab tests supporting public health and environmental programs

- Obj. 4.1 Maintain proficiency testing score of bacterial disease testing at 98%
Actual overall score = 100%
- Obj. 4.2 Maintain proficiency testing score of viral disease testing at 98%
Actual overall score = 100%
- Obj. 4.3 Maintain proficiency testing score of environmental testing at 95%
Actual overall score = 97%
- Obj. 4.4 Maintain proficiency testing score of hereditary disorders testing at 98%
Actual overall score = 100%

Other Fiscal Year 2005 Achievements

Disease Prevention and Control:

- Tested 26,524 specimens for tuberculosis and identified 65% (158/243) positive specimens and cultures within 72 hours.
- Presumptively identified 13 treatable hereditary disorders in every 1,000 newborns screened for 32 hereditary disorders, saving the State several million dollars in long-term care costs;
- Expanded the Emerging Infections Program under a federal grant to identify and provide to CDC additional pathogens to help ensure epidemiological surveillance in the State;
- Tested pools of all HIV antibody-negative specimens by RT-PCR to detect pre-seroconverting HIV-1 infected patients to reduce the time between infection and disease detection;
- Registered/renewed 13,000 licenses to distribute, manufacture, or dispense controlled dangerous substances

New Tests/Services Developed or Implemented:

- Certified to test for cyanide in blood;
- Validated and implemented a new thyroxin/thyroid stimulating hormone (T₄/TSH) testing system that does not involve the use of radionuclides; and
- Validated a method to analyze human urine for the presence of pyrethroid pesticides.

New Partnerships/Studies:

- Began analyzing human urine for exposure to heavy metals and pesticides [partnering with the DHMH Community & Family Health Administrations];
- Supporting development of a rapid, automated test for severe combined immunodeficiency (SCID) [partnering with the federal National Institutes of Health]; and
- Helping develop laboratory protocols for an analytical method that can rapidly detect a range of pathogenic and spoilage bacteria in food samples [partnering with the federal Food and Drug Administration].

Infrastructure Development:

- Renovated animal facility to provide new necropsy room and BSL-3 suite;
- Completed justification document for a new central public health laboratory;
- Completed implementation of a proximity card security system for all employees in the J. Mehser Joseph Public Health Laboratory;
- Drafted and procured a \$1.1M-contract for software to implement a new laboratory information management system (LIMS);
- Obtained freeze exemptions, recruited for, and filled 17 vacancies;
- Contracted with an architectural firm to help the Department prepare a formal planning document for a new central public health laboratory;
- Developed a graduate tuition reimbursement program to recruit public health laboratory scientists and to plan for succession by promoting from within the Administration;
- Implemented an ASR to update class specifications and salaries for public health laboratory scientists;
- Revised, printed, and distributed new edition to the *Guide for Public Health Laboratory Services*; and
- Promulgated: COMAR 10.10.01.03, “Rapid HIV Testing”
COMAR 10.10.08, “Medical Laboratories—Sanctions”

Laboratory Emergency/Terrorism Preparedness and Response:

- Established a surge capacity BioWatch laboratory to detect airborne BT agents in the National Capital Region using equipment and protocols provided by the federal Department of Homeland Security;
- Chemical Terrorism Laboratory was certification to reliably detect metabolites of cyanide in human blood and heavy metals in urine;
- Maintained a force of 154 emergency essential employees who are on-call to work 24/7/365 in response to a terrorist event or other public health emergency;

- Maintained emergency on-call laboratory communications (24/7/365);
- Maintained emergency mutual aid agreements with public health laboratories in Virginia and North Carolina;
- Prepared and distributed three issues of the “Laboratory Emergency Preparedness Newsletter” to first responders and sentinel laboratories throughout the State.

Procured New Laboratory Instrumentation/Equipment with Federal Grants:

Biomonitoring Laboratory:

- Gilson robotic liquid handler to dispense specimens and reagents \$25,000
- Freeze dryer (lyophilizer) to remove moisture from urine samples \$26,000

Food Safety Chemistry Laboratory:

- Gas chromatograph (GC) to test for pesticides in foods \$70,000
- Fat extractor to determine percentage fats in solid foods \$18,000
- High performance liquid chromatograph (HPLC) for foods \$36,000

BSL-3 Animal Facility:

- Animal waste disposal biological safety cabinet \$12,000
- Two down-draft necropsy tables \$24,000
- Two electric autoclaves \$17,500
- Three Sanyo carbon dioxide incubators \$18,500

LRN Bioterrorism Laboratory:

- Bio-Plex Microsphere Detection System (Lumenix) \$55,000

Molecular Diagnostics Laboratory:

- ABI 7500 Real-time PCR instrument \$42,000
- Two UPS power supplies for Real-time PCR instruments \$ 8,000

Arbovirus Serology Laboratory:

- Bio-Plex Microsphere Detection System (Lumenix) \$55,000

Molecular Epidemiology Laboratory:

- Bio-Rad Chef Mapper PFGE System \$21,000
- Bio-Rad Digital Imaging System (Gel-Doc for PFGE) \$ 8,000

Total \$435,500

Fiscal Year 2007 Initiatives for Which Funding Was Requested

An increase in the fee charged for a controlled dangerous substance certificate will be used by the Laboratories Administration to rebuild the under-funded and staff-depleted Drug Control Program that, in FY2005, was unable to issue controlled dangerous substance certificates within its annual issuing deadline.

The new permit fee (\$144 for two years) will generate \$1,672,800 in FY 2006, all of which will revert to the General Fund. This represents an increase of \$766,800 over the \$906,000 in the FY2006 revenue estimates. This same revenue figure will repeat in FY2007. However, for FY2007 DHMH has requested a budget increase of \$744,158 to:

- 1) Support three additional positions (1 pharmacist, 1 webmaster, and 1 clerical position);

- 2) Develop an on-line system for customers to apply for licenses over the Internet; and
- 3) Maintain the Drug Control Program's newly developed operational software (STARLIMS Sunrise).

Fiscal Year 2006-07 Goals

- Validate and implement cystic fibrosis screening of Maryland's newborns;
- Begin rebuilding the Division of Drug Control (staff, equipment, interactive licensing software) using increased licensing fees;
- Undergo federal re-certification as a select-agent laboratory by CDC;
- Undergo federal re-certification of dairy chemistry laboratory by FDA;
- Implement a new \$1.1M laboratory information management system (LIMS);
- Promulgate: COMAR 10.10.11, "Biological Agents Registry Program"
COMAR 10.10.13, "Medical laboratories—Testing for Hereditary and Congenital Disorders in Newborn Infants"; and
COMAR 10.19.03, "Controlled Dangerous Substances";
- Commission three biosafety level 3 laboratories;
- Prepare an RFP and contract with an architectural firm to design and construct a new central public health laboratory;